SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		74 Years	Male	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Heart Failure [Cardiac failure]	DAPAGLIFLOZIN, METFORMIN	Yes	No	Not Applicable	Related
Senile Dementia [Senile dementia]	DAPAGLIFLOZIN, METFORMIN	Yes	No	Not Applicable	Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☒ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet

15. DAILY DOSE(S)
#1) UNK mg, qd

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) (Not Coded)

18. THERAPY DATES(from/to)
#1) Unknown

19. THERAPY DURATION
#1) Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☐ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates | Type of History / Notes | Description
Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: CR-ASTRAZENECA-202507CAM023371CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00919490A

24b. MFR CONTROL NO.
202507CAM023371CR

24c. DATE RECEIVED BY MANUFACTURER
28-JUL-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
01-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a male elderly patient born in 1950 (age 74 years).

No medical history was reported. No concomitant products were reported.

On an unknown date, the patient started treatment with Dapagliflozin, Metformin (dapagliflozin, metformin) UNK mg, qd, Oral use.

On an unknown date, the patient experienced heart failure (preferred term: Cardiac failure) and senile dementia (preferred term: Senile dementia).

It was unknown if any action was taken with Dapagliflozin, Metformin.

At the time of reporting, the event heart failure and senile dementia was ongoing.

The events of Heart failure and Senile dementia were upgraded by the company physician from non-serious to serious due to Medically Significant criterion.

The reporter did not assess causality for heart failure and senile dementia.
The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following events: heart failure and senile dementia.

Company Clinical Comment: Cardiac failure and Senile dementia are not listed event in the core data sheet for Dapagliflozin, metformin. Elderly age could be risk factor. Due to limited information on circumstances leading to the event, clinical course, treatment provided, relevant medical history, risk factors, concurrent diseases, concomitant medications, status of underlying malignancy, complete etiologic and diagnostic workup, the evaluation did not find evidence to exclude a reasonable possibility of a causal relationship between events and suspect drug.